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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,207	06/30/2003	Monroe E. Wall	212405US23	7659
22850	7590	06/01/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/608,207

### Applicant(s)

WALL ET AL.

### Examiner

Rita J. Desai

### Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12, 14, 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/30/03</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

### DETAILED ACTION

Applicants request to make the application special has been granted.

An action o the application follows.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 13 in part , drawn to compounds and pharmaceuticals wherein R7 is a CO ... substituent and R10 or R11 is an amino acid , classified in class 546 and 514 and various subclasses.
- II. Claims 1-11, 13 in part , drawn to compounds and pharmaceutical compositions of formula I, W, X, y R13 and R14 do not contain a hetero ring and R7 is a Hydrogen, classified in class 546 , 514 and in various subclasses.
- III. Claims 1-11, 13 in part , drawn to compounds and pharmaceutical compositions of formula II wherein R7 is a Hydrogen and all other X,Y, R13, R14 substituents do not contain a hetero ring , classified in class 546 , 514 and various subclasses.
- IV. Claims 1-11, 13 in part , drawn to compounds and pharmaceuticals not covered by any of the groups I-III as given above, classified in various classes and subclasses. May be subject to furteher restriction. A further election of a single disclosed species is required.
- V. Claims 12, 14 drawn to methods of treating using these compounds , classified in class 514 and various subclasses.
- VI. Claim 15 drawn to a process of making the compounds.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have a different core and of formula I and II. and with the various substituents have different properties and different bonding.

Inventions I-IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there are several drugs that can be used for treating leukemia or tumors .

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Derek Mason on 5/27/2004 a provisional election was made with traverse to prosecute the invention of Group III , claims 1-11,13 in part drawn to compounds and pharmaceutical compositions of formula II wherein R7 is a Hydrogen and all other X,Y, R13, R14 substituents do not contain a hetero ring , classified in class 546 , 514 and various subclasses.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 12,14, 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder:

If the compounds are found to be allowable examiner will rejoin ONE method of treating and process of making , limited to the scope of the allowable compounds.

Applicants preserve their right to file a divisional on the cancelled non-elected subject matter without prejudice in due course.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

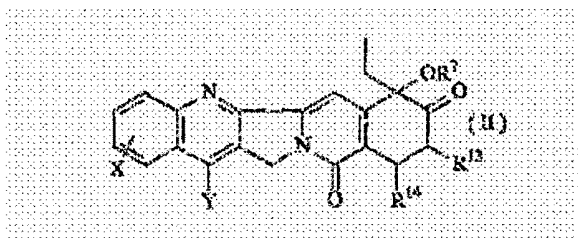
Claims 1-11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by EP

1101765, Gilbert L et al.

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Applicants elected group is drawn to

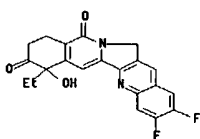
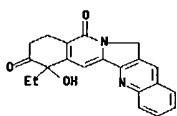
Compounds of the formula



wherein R<sup>7</sup> is a hydrogen and X, Y R<sup>13</sup>,

R<sup>14</sup> substituents can be hydrogen.

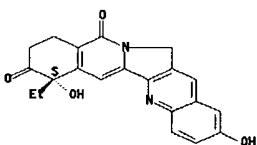
The reference clearly discloses the compounds .



Claims 1-11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US

6043367 Roffler, Steve et al.

The reference discloses



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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP

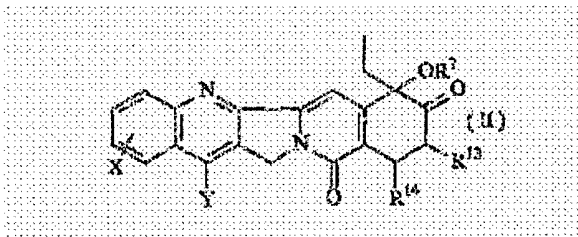
1101765, Gilbert L et al.

Lavielle et al US 6699876 (102e date) and 6509345

6043367 Roffler, Steve et al.

Applicants elected group is drawn to

Compounds of the formula



wherein R7 is a hydrogen and X, Y R13,

R14 substituents can be hydrogen.

Determination of the scope and content of the prior art (MPEP §2141.01)

Gilbert Lavielle et al discloses the camptothecin analogs with the various substituents at the X, Y, R13 and R14 positions.

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Among the substituents are hydroxy, halogen alkyl, alkoxy as such.

US 6699876 and US 6509345 Lavielle et al also teaches the various camptothecin analogs

with the various R<sub>1</sub>, -R<sub>5</sub> , substituents such as

R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> are selected from hydrogen, halogen, alkyl, alkenyl, alkynyl, perhaloalkyl, cycloalkyl, cycloalkylalkyl, hydroxy, hydroxyalkyl, alkoxy, alkoxyalkyl, alkoxycarbonyl, acyloxy, carboxy, nitro, cyano, aminocarbonyl (optionally substituted), and the groups (CH<sub>2</sub>)<sub>p</sub>-NR<sub>6</sub>R<sub>7</sub> and -O-C(O)-N-R<sub>8</sub>R<sub>9</sub>, with p, R<sub>6</sub> and R<sub>7</sub> being as defined in the description, or two adjacent groups R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> together form a group -O-(CH<sub>2</sub>)<sub>t</sub>-O, t being an integer from 1 to 3,

R<sub>100</sub>, R<sub>700</sub>, R<sub>80</sub> and R<sub>90</sub> represent a hydrogen atom, a hydroxy group, an alkoxy group, or an O-(CO)-X or O-(CO)-NXW group as defined in the description,

R<sub>61</sub>, R<sub>71</sub>, R<sub>81</sub> and R<sub>91</sub> represent a hydrogen atom, alkyl, alkenyl or alkynyl, or taken in pairs together form a bond or an oxirane group, or two groups together form an oxo group.

and medicinal products containing the same are useful for the treatment of cancerous diseases.

6043367 Roffler, Steve et al teaches the isomers

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The compounds are generically claimed within the prior art .

The specific S and r isomer is not disclosed.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The compounds of the prior art are racemic mixtures . The reference is silent as to the specific S or R isomer. But it is prima facie obvious for one skilled in the art to make the S or R isomer or a racemic mixture , or a mixture in which one isomer is in excess of the other.

### ***Conclusion***

The claims are not found to be allowable.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita J. Desai  
Primary Examiner  
Art Unit 1625

5/27/04

R.D.  
May 27, 2004